DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Pentacel
Patent Nos. 5,877,298 and 6,696,065
Docket Nos. FDA-2009-E-022
FDA-2009-E-0093

AUG 19 2009

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent numbers 5,877,298 and 6,696,065 filed by Sanofi Pasteur Limited (Sanofi Pasteur), under 35 U.S.C. § 156. The human biological product claimed by the patents is Pentacel (DTaP-IPV/Hib vaccine), which was assigned biologics license application (BLA) No. 125145.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that Pentacel does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1). The active ingredients in Pentacel have each been previously approved for commercial marketing or use in Sanofi Pasteur's products, Daptacel (DTaP vaccine), Poliovax (IPV) and ActHib (Hib).

The BLA was approved on June 20, 2008, which makes the submission of the patent term extension application on August 15, 2008, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Reza Yacoob
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